K083602

SEP - 8 2009

510(k) Summary

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Date of Preparation of this Summary:	July 10th, 2009
Device Trade or Proprietary Name:	Kappa light chains Assay
Classification Name:	Immunoglobulin (light chain specific) immunological test system.
Classification Number/Class:	Class II / 866.5550
Product Code:	DFH

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K083602

Test Description:

The Kappa light chains assay is an *in vitro* diagnostic test used for the quantitative determination of immunoglobulin bound and free kappa light chains (KAPPA) in serum and in Li-heparin plasma by immunoturbidimetry on Synchron LX20 System. Measurement of type of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus, in conjunction with other clinical and laboratory findings.

The determination of Kappa light chains is based on the specific turbidimetric reaction, which occurs between a polyclonal antiserum against human Immunoglobulin Kappa light chains and its corresponding antigen under optimal pH conditions and in the presence of polyethylene glycol (PEG). The turbidity of the immune complex is proportional to the concentration of the analyte in the sample.

Substantial Equivalence:

The Kappa light chains assay is substantially equivalent to Beckman IMMAGE Immunochemistry System Kappa light chain (K964260) on the IMMAGE nephelometer Analyzer. Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are used for the quantitative determination of Kappa light chains (free and bound).
- Both assays are based on immunologic reaction between the Kappa light chains of human immunoglobulin and a specific polyclonal.
- Both assay detect bound and free Kappa light chains
- Both assays utilize reagents in R1 and R2 format.
- Both assays are traceable to ERM-DA 470 (European Reference Material) from BCR (EG Community Bureau of Reference), corresponding to RPPHS (Reference Preparation for Protein in Human Serum).
- Both assays yield similar clinical results.

Differences:

- The predicate device assay uses serum only as specimens. Sentinel assay uses serum and Li- heparin plasma.
- The predicate device quantificates Kappa light chains by nephelometry. Sentinel assay quantificates Kappa light chains by immunoturbidimetry.
- In the predicate device, Kappa values are given in mg/dL and expressed as "equivalent weight of the intact immunoglobulin molecules (IgG + IgA + IgM = Kappa + Lambda). Thus the Molecular Weight of the Light chains is considered to be 150000 dalton (as the MW of whole IgG).
- In the Sentinel assay, Kappa values are given in mg/dL and expressed as content of Immunoglobulin light chains. The Molecular Weight of the Light chains is estimated to be 25000 dalton. Therefore, the results on Beckman Immage are about 3 times higher than results on Synchron LX.

Intended Use:

The Kappa light chains assay is an *in vitro* diagnostic test used for the quantitative determination of immunoglobulin bound and free kappa light chains (KAPPA) in serum and in Li-heparin plasma by immunoturbidimetry on Synchron LX20 System. Measurement of type of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus, in conjunction with other clinical and laboratory findings.

Performance Characteristics:

Comparative performance studies were conducted using the Synchron LX20 System. Sentinel Kappa light chains on Synchron LX20 System method comparison yielded acceptable correlation with the Beckman Kappa light chain (K964260) on IMMAGE nephelometer Analyzer.

Method comparison

Kappa light chains assay on Synchron LX20 System was calibrated with a calibrator material with assigned Kappa Light chains concentration based on definition of Kappa Light chains as Whole IgG content (MW 150000).

This comparison showed a correlation coefficient (r) of 0.985, slope of 0.900 and Y-intercept of 134 mg/dL.

Conclusion - Data generated demonstrated an acceptable correlation between the Kappa Light chains assay on the Synchron LX20 System vs. the IMMAGE Immunochemistry System Kappa light chains (K964260) on IMMAGE nephelometer Analyzer.

Precision:

Precision studies were conducted using Kappa light chains on the Synchron LX20 System. The found %CV values for 20x2x2 test (day x run x rep) on 6 levels (N=80 for each level) were:

Mean (mg/dL)	Total Imprecision		Between days		Repeatability (Repeatibility)	
	SD (mg/dL)	CV%	SD (mg/dL)	CV%	SD (mg/dL)	CV%
125.7	8.55	6.8	6.88	5.5	5.08	4.1
476.9	14.54	3.0	12.34	2.6	7.7	1.6
93.5	5.63	6.0	3.33	3.6	3.44	3.7
104.4	4.46	4.3	3.74	3.6	1.55	1.5
651.9	25.27	3.9	22.40	3.4	11.69	1.8
695.0	16.76	2.4	11.59	1.7	12.11	1.7

Analytical Measurement Range (AMR):

The found lower limit of the AMR of Lambda light chains on the Synchron LX20 System was 31.2 mg/dL. The found upper limit of the AMR was 750.13 mg/dL.

The claimed AMR will be 35 to 750 mg/dL.

Conclusion for 510(k) Summary:

These method comparison, precision and AMR data demonstrate that the analytical performance of the Kappa light chains on the Synchron LX20 System is substantially equivalent to IMMAGE Immunochemistry System Kappa light chain (K964260) on the IMMAGE nephelometer Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

SENTINEL CH SpA
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Regulatory Affairs
Via Robert Koch, 2
20152 Milan
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SEP - 3 2009

Re: k083602
Trade/Device Name: Kappa Light Chains Assay
Regulation Number: 21 CFR §866.5550
Regulation Name: Immunoglobulin (light chain specific) immunological test system
Regulatory Class: Class II
Product Code: DFH
Dated: August 26, 2009
Received: August 31, 2009

Dear Dr. Portelles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

maria m chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083602

Device Name: Kappa light chains

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The Kappa light chains assay is an *in vitro* diagnostic test used for the quantitative determination of immunoglobulin bound and free kappa light chains (KAPPA) in serum and in Li-heparin plasma by immunoturbidimetry on Synchron LX20 System. Measurement of type of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus, in conjunction with other clinical and laboratory findings.

Prescription Use X AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics Devices (OIVD)

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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